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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X	
IN RE:	:
Fosamax Products Liability Litigation	: 1:06-md-1789 (JFK)
	:
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<i>This Document Relates to:</i>	:
Ella Tristano, Individually, and On Behalf	:
Of All Others Similarly Situated	:
v. Novartis Pharmaceuticals Corporation	:
and Merck & Co., Inc.	:
	:
Case No: 1:07-cv-09562-JFK	:
-----X	

Defendant Merck & Co., Inc. ("Merck"), by its undersigned attorney, answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

1. Merck admits that Plaintiff purports to bring a civil action for damages, but denies that there is any legal or factual basis for same. Merck denies all remaining allegations of Paragraph 1, except that Merck states that it is without knowledge or information as to whether Plaintiff was prescribed and was injected with Zometa or was prescribed and ingested FOSAMAX®.

2. Merck admits that Plaintiff purports to bring a civil class action seeking a Court-supervised dental monitoring program, but denies that there is any legal or factual basis for same. Merck denies all remaining allegations of Paragraph 2.

PARTIES

3. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of Paragraph 3.

4. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of Paragraph 4.

5. Merck admits the allegations of Paragraph 5.

6. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations against Novartis Corporation ("Novartis") in Paragraph

6. Merck admits that it is registered to do business in the State of New Jersey and denies the remaining allegations of Paragraph 6.

JURISDICTION AND VENUE

7. The allegations contained in Paragraph 7 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 7.

8. The allegations contained in Paragraph 8 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 8, except states that it is without knowledge as to the residence of Plaintiff.

FACTS

9. The allegations of Paragraph 9 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 9.

10. The allegations of Paragraph 10 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 10.

11. The allegations of Paragraph 11 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 11.

12. The allegations of Paragraph 12 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 12.

13. The allegations of Paragraph 13 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 13.

14. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 14, except that it admits that Ruggiero, et

al., published an article entitled, “Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases,” Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004) and respectfully refers the Court to said article for its actual language and full text.

15. The allegations of Paragraph 15 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 15.

16. The allegations of Paragraph 16 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 16.

17. The allegations of Paragraph 17 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

19. Merck admits that FOSAMAX® is a prescription medication approved by the federal Food and Drug Administration (“FDA”) for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 19 inconsistent with that prescribing information.

20. Merck admits that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 20 inconsistent with that prescribing information.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. The allegations of Paragraph 26 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 26.

27. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the statement that Plaintiff took FOSAMAX®. Merck denies each and every remaining allegation of Paragraph 27, including each and every allegation of subparagraphs (a) through (g).

CLASS ACTION ALLEGATIONS

28. Merck repleads its answers to Paragraphs 1 through and including 27, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

29. Merck admits that Plaintiff purports to bring a civil class action, but denies that there is any legal or factual basis for same. Merck denies all remaining allegations of Paragraph 29.

30. Merck admits that Plaintiff purports to bring a civil class action and seeks to be a class representative, but denies that there is any legal or factual basis for same. Merck denies all remaining allegations of Paragraph 30.

31. Paragraph 31 simply seeks to define the class Plaintiff purports to represent and therefore no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32, except Merck admits the allegations of the first sentence of Paragraph (d), admits that FOSAMAX® is sold throughout the United States, and admits that the volume of sales of FOSAMAX® in any one state has varied over time. Merck states that it is without knowledge or information sufficient to form a belief as to the allegations related to Zometa in subparagraphs (a) through (c). Merck denies all remaining allegations of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

34. Merck denies each and every allegation of Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40, including each and every allegation of subparagraphs (a) through (g).

41. Merck denies each and every allegation of Paragraph 41, including each and every allegation of subparagraphs (a) through (f).

42. Merck denies each and every allegation of Paragraph 42.

43. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

COUNT I

AS AND FOR A FIRST CAUSE OF ACTION UNDER THE NEW JERSEY PRODUCTS LIABILITY ACT

45. Merck repleads its answers to Paragraphs 1 through and including 44, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

46. Merck denies each and every allegation of Paragraph 46.

47. The allegations of Paragraph 47 state a legal conclusion to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 47 and respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. The allegations of Paragraph 50 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that

it is without knowledge sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 50.

51. Merck denies each and every allegation of Paragraph 51, except Merck states that it is without knowledge as to whether Plaintiff was prescribed and ingested FOSAMAX®.

COUNT II

AS AND FOR A SECOND CAUSE OF ACTION FOR STRICT PRODUCT LIABILITY – DESIGN DEFECT

52. Merck repleads its answers to Paragraphs 1 through and including 51, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

53. The allegations of Paragraph 53 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 53.

54. The allegations of Paragraph 54 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 54.

55. The allegations of Paragraph 55 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 55.

56. The allegations of Paragraph 56 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 56.

57. The allegations of Paragraph 57 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 57.

58. The allegations of Paragraph 58 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

COUNT III

**AS AND FOR A THIRD CAUSE OF ACTION FOR
STRICT PRODUCT LIABILITY – FAILURE TO WARN**

65. Merck repleads its answers to Paragraphs 1 through and including 64, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

66. The allegations of Paragraph 66 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 66.

67. The allegations of Paragraph 67 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 67.

68. The allegations of Paragraph 68 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 68.

69. The allegations of Paragraph 69 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

COUNT IV

AS AND FOR A FOURTH CAUSE OF ACTION FOR NEGLIGENCE

74. Merck repleads its answers to Paragraphs 1 through and including 73, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

75. The allegations of Paragraph 75 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 75.

76. The allegations of Paragraph 76 are not directed to Merck and merely state a legal conclusion and therefore Merck is not required to respond. To the extent a response is required, Merck refers the Court to the relevant legal standard, including any conflict of law rules.

77. The allegations of Paragraph 77 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 77.

78. The allegations of Paragraph 78 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 78.

79. The allegations of Paragraph 79 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 79.

80. Merck denies each and every allegation of Paragraph 80, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX®.

81. The allegations of Paragraph 81 state a legal conclusion to which Merck is not required to respond. To the extent a response is required, Merck denies each and every allegation of Paragraph 81 and respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

COUNT V

AS AND FOR A FIFTH CAUSE OF ACTION FOR BREACH OF EXPRESS WARRANTY

85. Merck repleads its answers to Paragraphs 1 through and including 84, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

86. The allegations of Paragraph 86 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 86.

87. The allegations of Paragraph 87 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 87.

88. The allegations of Paragraph 88 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 88.

89. The allegations of Paragraph 89 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

91. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

COUNT VI

**AS AND FOR A SIXTH CAUSE OF ACTION
FOR BREACH OF IMPLIED WARRANTY**

94. Merck repleads its answers to Paragraphs 1 through and including 93, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

95. The allegations of Paragraph 95 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 95.

96. The allegations of Paragraph 96 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 96.

97. The allegations of Paragraph 97 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 97.

98. The allegations of Paragraph 98 are not directed to Merck and therefore Merck is not required to respond. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

100. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

COUNT VI¹

**AS AND FOR A SEVENTH CAUSE OF ACTION
FOR PUNITIVE DAMAGES**

103. Merck repleads its answers to Paragraphs 1 through and including 102, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

104. Merck denies each and every allegation of Paragraph 104.

105. Merck denies each and every allegation of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

COUNT VII²

**AS AND FOR A SEVENTH CAUSE OF ACTION
FOR DENTAL MONITORING**

107. Merck repleads its answers to Paragraphs 1 through and including 106, and by this reference hereby incorporates the same herein in this paragraph, and makes

¹ Although labeled Count VI, this is actually the Seventh Cause of Action stated in the Complaint.

² Although labeled Couth VII, this is actually the Eighth Cause of Action stated in the Complaint.

the same a part hereof as though fully set forth *verbatim*. Merck further denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

109. Merck denies each and every allegation of Paragraph 109.

110. Merck denies each and every allegation of Paragraph 110.

111. Merck denies each and every allegation of Paragraph 111.

PRAYER FOR RELIEF

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

ADDITIONAL DEFENSES

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiff's Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

FIRST ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND ADDITIONAL DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD ADDITIONAL DEFENSE

This case is more appropriately brought in a different venue.

FOURTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH ADDITIONAL DEFENSE

Plaintiff is barred from recovering against Merck because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by applicable federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq.

SIXTH ADDITIONAL DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to prescribing physician. Plaintiff's claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warning to prescribing physicians.

SEVENTH ADDITIONAL DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned or reduced in accordance with the applicable law.

EIGHTH ADDITIONAL DEFENSE

The injuries and damages, if any, sustained by Plaintiff resulted in whole or in part from their own contributory or comparative negligence and any damages recovered should be reduced and/or barred in accordance with the applicable law.

NINTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH ADDITIONAL DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH ADDITIONAL DEFENSE

Plaintiff's claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiff seeks punitive damages, such claims are barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST ADDITIONAL DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND ADDITIONAL DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD ADDITIONAL DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part by failure to prevent or mitigate damages.

TWENTY-FIFTH ADDITIONAL DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH ADDITIONAL DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH ADDITIONAL DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States of America and the Constitution of the State of New Jersey.

THIRTIETH ADDITIONAL DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST ADDITIONAL DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available

medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND ADDITIONAL DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD ADDITIONAL DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH ADDITIONAL DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH ADDITIONAL DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH ADDITIONAL DEFENSE

Plaintiff's claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH ADDITIONAL DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

THIRTY-EIGHTH ADDITIONAL DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling

for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

THIRTY-NINTH ADDITIONAL DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTIETH ADDITIONAL DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including FOSAMAX®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

FORTY-FIRST ADDITIONAL DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

FORTY-SECOND ADDITIONAL DEFENSE

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiff.

FORTY-THIRD ADDITIONAL DEFENSE

To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

FORTY-FOURTH ADDITIONAL DEFENSE

To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any source for injuries in the Complaint, such benefits are not recoverable in this action under N.J.S.A. 2A:15-97.

FORTY-FIFTH ADDITIONAL DEFENSE

The defendant is not guilty of negligence and violated no duty owing to Plaintiff.

FORTY-SIXTH ADDITIONAL DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity and/or standing to bring such claims.

FORTY-SEVENTH ADDITIONAL DEFENSE

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

FORTY-EIGHTH ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, res judicata, payment and/or release.

FORTY-NINTH ADDITIONAL DEFENSE

Plaintiff's damages are barred or reduced by the doctrine of avoidable consequences.

FIFTIETH ADDITIONAL DEFENSE

With respect to Plaintiff's demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North

America v. Gore, 116 U.S. 1589 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mut. Auto. Ins. Co. v. Campbell, 123 S.Ct. 1513 (U.S. 2003).

FIFTY-FIRST ADDITIONAL DEFENSE

To the extent that Plaintiff attempts to seek equitable relief, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

FIFTY-SECOND ADDITIONAL DEFENSE

Plaintiff is barred from recovery and/or Plaintiff's recovery is limited pursuant to the Comparative Negligence Act, N.J.S.A. 2A:15-5.1, et seq.

FIFTY-THIRD ADDITIONAL DEFENSE

Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiff, then it shall only be liable for its equitable share of Plaintiff's recovery since any liability which would be found against it will be insufficient to impose joint liability. In the alternative, the liability, if any, of Merck is limited by and pursuant to the New Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, et seq.

FIFTY-FOURTH ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel or waiver.

FIFTY-FIFTH ADDITIONAL DEFENSE

Merck asserts all defenses available to it pursuant to N.J.S.A. 2A:58C-1, et seq., otherwise known as the New Jersey Product Liability Act.

FIFTY-SIXTH ADDITIONAL DEFENSE

Plaintiff fails to state a claim upon which relief can be granted for medical monitoring or compensation for medical monitoring.

FIFTY-SEVENTH ADDITIONAL DEFENSE

The class allegations are barred in that if this action is certified as a class action, Merck's rights under the Fifth and Seventh Amendments of the United States Constitution and comparable provisions of the New Jersey State Constitution would be violated.

FIFTY-EIGHTH ADDITIONAL DEFENSE

Plaintiff lacks standing because this action has not been brought by a competent plaintiff for the benefit of allegedly injured parties.

FIFTY-NINTH ADDITIONAL DEFENSE

Plaintiff's claims for medical monitoring are not appropriate for class action treatment.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
February 6, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: _____/s/_____
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